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HIPAA threatens clinical research

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In the 50s, our mothers told us to avoid crowds and public swimming pools. The polio vaccine changed that. Medical research got us the polio vaccine, not HIPAA, not the Belmont Report, not advocates for patient safety. But clinical research, which is research done on humans, is now hobbled by HIPAA, blocked by Belmont, and penalized in the name of patient safety. It's time for a change.

HIPAA, the Health Insurance Portability Accountability Act, carries many burdens, some of which are increasing requirements for documentation in clinical research. Consent forms have ballooned from one or two pages, just 15 years ago, to up to 20 pages now. Just the boilerplate "HIPAA language" occupies over a page. It discusses the use of one's health care information, and the need to safeguard privacy. Doctors, clinical researchers, and medical institutes are thus held to strict standards, but will an insurance company truly keep your health care information private? After all, claims adjusters need this information to be able to reject your claim.

The Belmont Report, near 30 years old, claims to be a landmark statement about the rights of human subjects in research. It waxes eloquent about the trespasses of Tuskegee and Willowbrook. Its heirs and assigns are in the patient safety advocate groups, who believe that yet more paperwork is the answer. So medical researchers cannot even talk to potential participants in a study unless they have permission to do so. We cannot even review existing medical records for that purpose. Confidentiality risks, say the patient advocates. As a doctor, patient, and five-time participant in medical research studies done on myself, I say "'tis nonsense". There is no risk to having one's chart reviewed for a possible medical study. There is no risk in being asked to participate in a medical study. There is potential gain in participating, for oneself, and for society. By increasing the paperwork, by establishing these impediments, we are compromising ourselves. By trying to reduce risk, we are risking our future. We are hobbling research. We are not learning what we need to learn to make the world a better place. It's time for a change.

Moreover, HIPAA is expensive. It costs money to pay for the growing group of support staff who submit the protocols, copy the consent forms, and monitor the review board websites. That money pays for bureaucracy, not for patient care, not for creation of new knowledge.

Tuskegee.....not the airmen, but the syphilis study, is a stain on the record of medical research. To leave syphilis untreated, for years, without consent, is what was done. Terrible, wrong, unjust, and unfair. But also behind us. Informed consent is now routine. Let us instead celebrate what has been right about medical research. Let us remember Emile Roux who tested treatments for diphtheria. That dread disease killed children as a matter of routine 100 years ago. Roux did not have HIPAA shackling him. His work, and that of others, conquered that disease.

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Diphtheria is now a curiosity, no longer a dread disease. Jenner perfected vaccination, two hundred years ago. No HIPAA, no Belmont, no patient safety advocates. Jenner's work led to the eradication of smallpox. Our present day fear of that disease is a clear statement of the enormous debt we owe to Jenner, not to HIPAA. Antisepsis for surgery is a recent concept; only a century has passed since Lister's time. The Royal Infirmary in Glasgow had no HIPAA committee, no 17 page consent forms for use of carbolic acid and sterilization of the surgical field. Lister, Jenner, Roux – all worked as the ethical doctors that they were. We owe them a lot. We need to simplify the informed consent process, and reduce the paperwork that burdens Institutional Review Boards. It's time for a change.

Some will say "but research has killed some people". Gene therapy has gone awry. Nazi Germany did awful "experiments" on Jews in concentration camps. But the latter has been addressed and adjudicated. The former has been addressed by the legal system. Clinical research, in the overwhelming number of cases, has helped, not hurt. The few examples of past error should not force the system to be so cumbersome as to prevent new research. The HIPAA mandates need to be streamlined. Consent forms must be made shorter. Retrospective studies should be permitted with a minimum of paperwork.

Some will argue that the drug companies have pushed drugs on us that later had problems, even caused death. "Remember Oraflex!" they shout. Yes, it was bad stuff, even killed people. Inappropriate marketing contributed to the deaths of over 100 people related to Oraflex. But the same company has saved many millions of lives because of its essential role in the commercial development of insulin. Perhaps another company would have done that. But that company stepped up to the plate in 1923. Without HIPAA, without Belmont, and without Patient Safety advocates, they took Banting's discovery of insulin, and got that drug to the people. Without insulin, millions would die. Today.

It is a matter of numbers. Clinical research has helped far far more people than it has hurt. Medicine's research track record is not pure, but it is very very good. Its imperfections are like cracks in fine leather -- proof of authenticity. The patient safety people say they are helping to prevent abuses. What they really are doing is trying to stop clinical research.